RVD2008-17

Re-evaluation Decision

# Imazapyr

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# Overview

## Re-evaluation Decision

After a re-evaluation of the herbicide imazapyr, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing imazapyr for sale and use in Canada.

An evaluation of available scientific information found that products containing imazapyr do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of imazapyr uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of imazapyr was first presented in Proposed Re-evaluation Decision document PRVD2008-10, *Imazapyr*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of imazapyr as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-10. To comply with this decision, registrants of products containing imazapyr will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Imazapyr, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated imazapyr and published its conclusions in a 2006 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-10, *Imazapyr*.

## What Is Imazapyr?

Imazapyr is a herbicide used to control annual and perennial grasses, broadleaf weeds and select perennial shrubs and trees on the following non-crop, non-graze areas: forest sites being prepared by ground application, industrial sites, railroad ballast, spot application treatment for rail and hydro rights-of-way and stations associated with pipeline rights-of-way, including well sites, battery stations, and compressor or valve stations. It is applied using ground spray and hand-held equipment, typically by licensed applicators only.

## Health Considerations

### Can Approved Uses of Imazapyr Affect Human Health?

**Imazapyr is unlikely to affect your health when used according to the revised label directions.**

People could be exposed to imazapyr through consumption of water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that imazapyr was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

#### Maximum Residue Limits

Imazapyr is currently registered in Canada for use on non-crop, non-graze areas only (no food use registered). No Canadian residue limits have been established for imazapyr.

## Environmental Considerations

### What Happens When Imazapyr Is Introduced Into the Environment?

**Imazapyr is unlikely to affect non-target organisms when used according to the revised label directions.**

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to imazapyr in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of imazapyr was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require both aquatic and terrestrial buffer zones for imazapyr to protect both aquatic organisms and terrestrial plants from spray drift.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of imazapyr, the PMRA is requiring further risk-reduction measures for product labels.

**Human Health**

- A statement preventing workers and others from entering treated areas until sprays have dried.

**Environment**

- Buffer zones to protect sensitive aquatic and non-target terrestrial habitats.

Appendix I lists all required label amendments.

## Other Information

Any person may file a notice of objection[3] regarding this decision on imazapyr within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

# Appendix I Label Amendments for Products Containing Imazapyr

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statement must be included in the **PRECAUTIONS** section.

> Do not enter or allow others to enter treated areas until sprays have dried.

II) The following statements must be included in the **DIRECTIONS FOR USE** section.

> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height 60 cm or less above the weed canopy or ground.
>
> For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.
>
> DO NOT apply by air.
>
> **Buffer zones:**
>
> Use of the following spay methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| Method of Application | Use | Buffer Zones (metres) Required for the Protection of: | |
|---|---|---|---|
| | | Aquatic habitat | Terrestrial habitat |
| Field sprayer* | Non-crop, non-graze areas and forestry site preparation | 1 | 20** |

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

** Buffer zones for protection of terrestrial habitats are not required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements and roads.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

TOXIC to non-target aquatic and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.